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**IN THE UNITED STATES PATENT AND TRADEMARKS OFFICE**

Applicant: Lezdey  
Filed: 03/15/2004  
Serial No.: 10/801,419  
For: METHOD OF TREATMENT

Examiner: Betton  
Art Unit: 1614

Mail Stop – Amendment – No Fee  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL**

Dear Sir:

Please find enclosed for filing:

<input checked="" type="checkbox"/> Response & Interview Summary	<input type="checkbox"/> Check in the Amount of \$
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Date: October 10, 2007  
Docket No.: 1434-19

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John Lezdey  
SIGNATURE OF PERSON SIGNING CERTIFICATE DATE  
*John Lezdey* 10/10/2007

Respectfully submitted,

*John Lezdey*  
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**Response and Interview Summary**

Responsive to the Official Action dated September 7, 2007.

The interview with the Examiner is herewith noted with appreciation.

Claims 2, 4, 6 and 11-13 have been rejected under 35 USC 103(a) as being unpatentable over Lezdey et al, Henley et al in view of Weiner et al.

As discussed at the interview, Lezdey et al relates to healing burns and wounds with cromolyn, hyaluronic acid and amniotic fluid. The combination works synergistically to cause the proper laying down of tissue to promote healing without scarring.

Cromolyn prevents the degranulation of mast cells which are found in burns and wounds to prevent the release of cathepsin G and elastase that destroys healthy tissue. The amniotic fluid provides a proper growth environment and the hyaluronic acid promotes quicker tissue growth.

In contrast, in diaper rash and decubitus ulcers there is no need for new tissue. The rash is due to undesired tissue growth. The cromolyn prevents further rash and binds with mast cells that have been drawn to the area by receptors. The rash results from the

acid pH from the urine and bacteria which elevates TNF- $\alpha$  which degranulates mast cells and releases histamine release factors.

There is a difference in the mechanism of action of cromolyn in diaper rash and decubitus ulcers.

Henley et al discloses cromolyn but not for treating diaper rash and decubitus ulcers. Henley relates to electrokinetic delivery of a substance together with ultrasonic vibration which opens pores to deliver a medicament. Henley et al also teaches treatment of fungal infections of skin comprising diaper rash.

As discussed at the interview, cromolyn is not an anti-fungal agent. Henley et al does not teach using cromolyn for diaper rash. Applicants were the first to teach the use of cromolyn to treat diaper rash or decubitus ulcers.

It was further noted that electrokinetic delivery and ultrason vibration would not be suitable for burns since it leads to penetration of unwanted chemicals and would disrupt tissue in wound healing. Also, as a practical matter, diaper rash and decubitus ulcers cover a large area and are tender to the touch so that vibration would not be a desired method.

Decubitus ulcers are not caused by fungal infections. Urine, sweat and lack of movement by the patient are the likely cause. The decubitus ulcers lead to infection but not fungal infection.

Weiner et al is not at all pertinent to the present invention. The reference teaches the reaction of cyclodextrin with minoxidil to obtain penetration into hair follicles.

In contrast, there are no hair follicles in diaper rash and minoxidil does not react with cromolyn.

Moreover, one in the art would not use cyclodextrin on burns because it dissolves the lipid layers of the stratum cornea. There are no lipids in burns.

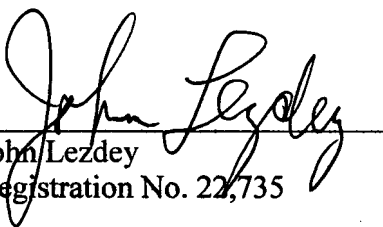
None of the cited reference ssolve the problems relating to diaper rash and decubitus ulcers.

Weiner et al does not teach cyclodextrin as a penetrating agent. Weiner et al teaches that the reaction product of cyclodextrin and minoxidil penetrates hair follicles and not the stratum cornea.

Consequently, the cited references fail to teach or suggest applicant's claimed invention.

Favorable action is earnestly solicited.

Respectfully submitted,



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